OCT 18 2011

K110021

510 (k) Summary of Safety and Effectiveness for DASH hip

Manufacturer/Submitter:

Address:	BrainLAB AG	
	Kapellenstrasse 12	
	85622 Feldkirchen	
	Germany	
	Phone:	+49 89 99 15 68 0
	Fax:	+49 89 99 15 68 33
Contact Person:	Mr. Alexander Schwiersch	

Summary Date: August 11, 2011

Device Name:

Trade name:	DASH hip
Common/Classification Name:	BrainLAB DASH, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
BrainLAB hip unlimited (K083483)
Kolibri Image Guided Surgery System (K014256)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II
Regulation Number: 21 CFR 882.4560
Product Code: OLO

Device Description:

DASH hip is intended to enable operational navigation in minimally invasive orthopedic surgery. It links a surgical instrument, tracked by passive markers to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. DASH hip uses the registered landmarks to determine postoperative changes in leg length and offset.

DASH hip software intraoperatively registers the patient data needed for navigating the surgery. No preoperative CT-scanning is necessary.

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Intended Use:

DASH hip is intended to be an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface.

The system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure, such as a long bone, can be identified relative to the anatomy. The system aids the surgeon in controlling leg length and offset discrepancies.

Example orthopedic surgical procedures include but are not limited to:

Total Hip Replacement (THR)
Revision surgery of THR
Minimally Invasive THR Surgery

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Changes made to the predicate device:

Reduced SW complexity: The spectrum of possible workflows in BrainLAB hip unlimited has been reduced to one single workflow. The initial version of the implemented workflow and algorithm for determining the changes in Leg Length and Offset, taken from BrainLAB hip unlimited, has been improved and adapted for use as Dash hip. This workflow employs a method which uses a non-invasive, externally-fixed femoral reference array. No further implant navigation steps are performed.

Reduced Platform: Compared to predicate device, the main calculation unit is part of the camera stand. The smaller separated display, represented by an iPod touch, acts as an embedded display within the instrumentation for used navigation.

Wireless communication between embedded display (iPod touch) and main calculation unit (integrated in camera stand).

Completed verification activities:

The following design verification activities have been performed to ensure correct system functionality according to its specifications:

- The first part of the verification covered the instrument and system accuracy during registration, post-operative point acquisition, and analysis. The registration values have been compared to externally-measured reference values. This has been completed for the registration (pre-operative) and post-operative repositioning and point acquisition (for final result analysis) to ensure the correct behavior of the pointer unit in conjunction with the software.

- In addition to the verification of the instruments in combination with the software, the verification of the software algorithm itself has been performed. With this step, the main software functionality has been successfully verified.

- Part three of the verification includes the testing of the workflow to ensure the correct behavior of the system.

- With the knowledge of the above named points, the current device was compared to the predicate device. This was done by comparing two systems directly during a simulated standard case, and a direct comparison of the used computer system.

- The next step was the detailed verification of the signed specifications covering the detailed functionality of the buttons, for example.

- Finally, the measures against the defined risks of the Risk Analysis have been tested.

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This strategy ensures the verification of the software algorithm, the combination of the software with the instrumentation, the comparison to the predicate device, and the safety of the defined measures of the Risk Analysis. All tests have been successfully completed.

Completed validation activities:

The following design validation activities have been performed:

- Literature research of Brainlab computer assisted total hip replacement software has been performed to ensure that Dash hip conforms to user needs and intended uses as well.

- The Non-clinical Validation was performed to confirm the system targets and to supplement requirement specifications where necessary. OR setups and surgical procedures have been simulated with plastic bone models (sawbones) in Usability Workshops (use labs).

- A Pre-clinical Validation was performed to confirm/ complete detailed specification for each requirement. Here, OR setups and surgical procedures were simulated in a cadaver lab. Testing persons went through the same procedure as for the Non-clinical use lab sessions.

- To prove that all validation issues are addressed, a Non-Clinical validation was performed under non-clinical conditions. This took place in three phases; the first phase occurring in St. Gallen, Switzerland, and the second in Portland, OR, USA, and the third, final phase in Feldkirchen, Germany. The final phase in Feldkirchen, Germany was used to confirm that any outstanding change requests from previous validation phases have been sufficiently implemented.

- The navigation accuracy of the leg length and offset measurements were evaluated in a prospective clinical study. Forty-three consecutive THR surgeries were analyzed. In this study, it is shown that the accuracy relating purely to the navigation measurements for leg length and offset is comparable to the previously used leg length and offset technique from the predicate device, which necessitated a femoral reference array invasively fixed within the bone. Thus, both techniques are considered to be equivalent.

Substantial equivalence:

Dash hip has been verified and validated according to BrainLAB's procedures for product design and development. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device BrainLAB hip unlimited (K083483) and Kolibri Image Guided Surgery System (K014256).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2011

BrainLAB AG
% Mr. Alexander Schwiersch
Kapellenstrasse 12
85622 Feldkirchen, Germany

Re: K110021
Trade/Device Name: DASH Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 19, 2011
Received: September 26, 2011

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K110021

Device Name: DASH hip

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Prescription Use ____X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110021